

### **SUPPLEMENTAL ACTION**

This Office Action supersedes the Office Action mailed on April 15, 2011. The previous Office Action cancelled Claim 35 by Examiner's Amendment, but failed to acknowledge that fact in the Notice of Allowability (form PTOL-37).

Claims 1 & 3-46 are pending; of which, Claims 3, 18-21, 23, 36, & 47 are currently amended. Claims 2 & 47 are cancelled.

### ***Response to Amendment***

Applicant's amendments to Claims 3, 18-21, 23, 36, & 47 have been fully considered and are entered. The status for each of the rejections and/or objections in the Office Action mailed October 12, 2010 is set out below.

The 103-prior art rejection of Claim 2 over US 6,528,660, WO 97/03959, and US 5,273,995 is withdrawn per cancellation of Claim 2.

The 112-indefinite rejection of Claim 47 as being an omnibus claim is withdrawn per cancellation of Claim 47.

The 112-indefinite rejection of Claims 3 & 4 for lacking antecedent basis is withdrawn per amendment.

The objection to Claims 18, 20, 21, 23, & 36 for being improper dependent claims is withdrawn per amendment.

The objection to Claims 19-21 is withdrawn.

***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James DeYonker on April 8, 2011.

The application has been amended as follows:

- 1.** In Claim 26, ***after*** ". . . suspended in 15 to 25 volumes" and ***before*** "of a mixture of methanol and water . . ." ***delete*** "(w.r.t. weight of atorvastatin calcium)" and ***insert*** - - (with respect to the weight of atorvastatin calcium) - -.
- 2.** In Claim 27, ***after*** ". . . suspended in 15 to 25 volumes" and ***before*** "of a mixture of methanol and water . . ." ***delete*** "(w.r.t. weight of atorvastatin calcium)" and ***insert*** - - (with respect to the weight of atorvastatin calcium) - -.
- 3.** ***Delete/Cancel Claim 35.***
- 4.** ***Add a new Claim 48 and insert*** - -  
48. (New) The process of claim 1, wherein the conversion to amorphous form comprises:
  - a) dissolving crystalline atorvastatin calcium and an antioxidant in a solvent;
  - b) adding the atorvastatin calcium and antioxidant solution to an antisolvent; and
  - c) separating precipitated, amorphous atorvastatin calcium from the resulting suspension to obtain stabilized, amorphous atorvastatin calcium. - - .

**5. Add a new Claim 49 and insert - -**

49. (New) The process of claim 1, wherein the conversion to amorphous form comprises:

- a) dissolving crystalline atorvastatin calcium in a hydroxylic solvent;
- b) adding the obtained solution of atorvastatin calcium to a non-hydroxylic antisolvent, wherein the non-hydroxylic anti-solvent has a higher boiling point than the hydroxylic solvent;
- c) concentrating the solution so obtained to remove the hydroxylic solvent; and
- d) separating precipitated, amorphous atorvastatin calcium from the resulting suspension to obtain amorphous atorvastatin calcium. - - .

**6. Add a new Claim 50 and insert - -**

50. (New) The process of claim 48 or 49, wherein an antioxidant is added to the solution of atorvastatin calcium in hydroxylic solvent. - - .

***Conclusion***

Claims 1, 3-34, 36-46, & 48-50 are allowed and renumbered Claims 1-47.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is [Jason.Nolan@uspto.gov](mailto:Jason.Nolan@uspto.gov). The examiner can normally be reached Monday - Friday (9:00AM - 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane, may be contacted at [Joseph.McKane@uspto.gov](mailto:Joseph.McKane@uspto.gov) or (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, (Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626